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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,555	01/27/2006	Menno Willem Jose Prins	NL030947	6159

24737 7590 05/11/2010

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
05/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

Priority

This application 10566555, PG Pub. No. 20060205093 filed 01/27/2006 is a national stage entry of PCT/IB04/51213 , International Filing Date: 07/14/2004 and claims foreign priority to 03102352.6 , filed 07/30/2003.

After-Final Amendment Entry & Claims Status

The amendments filed on March 30, 2010 has been acknowledged and entered.

Claims 18-24, 26-32 are pending and being examined.

Claimed Invention

18. (Previously Presented) A tool for distinguishing between bindings of different strengths between first and second microbiological entities, the tool comprising:

- first particles and second particles, at least one of which is magnetic,

- means for acting on the first and second particles to cause the first and second +particles to exert a mechanical stress on bindings between the first and second microbiological entities to distinguish between the bindings of different strengths, the means for acting on the first and second particles comprising at least a magnetic field generator.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-21, 22, 24, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (US 6,337,215).

Wilson teaches magnetic particles with different strengths of magnetic moments and/or different magnetic field dependencies for separating of several affinity partners simultaneously. Magnetic particles having different magnetic moments (magnetic particles with the first magnetic moment are equivalent to first particles; and magnetic particles with a second magnetic moment are equivalent to second particles of the present invention) are attached to different acceptor molecules (microbiological entity such as protein or peptide- see col. 16, lines 55-65; col. 19, lines 58-60) and a magnetic field generator (see col. 1, line 65-col. 2, line 28). When the particles are separated using a magnetic force, the application of such magnetic force draws the magnetic beads of same magnetic moments into a region determined by the magnetic field so that non-magnetic components can be eliminated. Beads with different magnetic moments are caused to move at different rates and thus the strengths of the particles are distinguished. Regarding claim 19, since Wilson teaches that the magnetic particles have different magnetic moments, it is inherent that the magnetic moment of one particle is greater or smaller than that of the other particle. Regarding claims 22 and 24,

since the present invention describes that the magnetic field generator is a means for exerting a mechanical stress, which also includes a means for exerting a fluid frictional force and means for generating an excitation that forces a lateral movement of the particles and Wilson teaches a magnetic field generator, such magnetic field generator is capable of exerting a fluid frictional force since Wilson teaches the particles are placed in a solution (see col. 16, lines 14-25 or fig. 7) and generating an excitation that forces the particles to move laterally. Regarding claim 31, since Wilson uses the same magnetic field generator for applying a magnetic field as claimed in the present invention, such magnetic field in Wilson would have the same magnetic vector with varying direction as a function of time.

Claims 18-24, 19, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Baselt et al. (Biosensors & Bioelectronics 13, 731-739, 1998).

Baselt teaches a biosensor that measures forces that bind DNA to DNA, antibody-antigen or ligand to receptor together. The bead array counter (BARC) uses these interaction forces to hold magnetic microbeads to a solid substrate. Microfabricated magnetoresistive transducers on the substrate indicate whether or not the beads are removed when pulled by magnetic forces. By adapting magnetoresistive computer memory technology, it is possible to fabricate millions of transducers on a chip and detect or screen thousands of analytes. (see abstract). Since Baselt teaches that multi- analytes are detected or screened, there must be more than one type of magnetic particles, one type for each different analyte. Baselt teaches that the target molecule

bridges the substrate and a magnetic microbead. (see pg 733, magnetic bead assays). Regarding claim 19, since Baselt teaches that the magnetic particles have different magnetic moments, it is inherent that the magnetic moment of one particle is greater or smaller than that of the other particle Thus, the magnetic beads are attached to the target molecule which is an antigen (protein) or DNA. Regarding claim 24, since the specification fails to describe any structure of the means for generating an excitation that forces a lateral movement of the particles with respect to the array, the magnetic field generator in Baselt is equivalent to such means because the magnetic field generator can be placed on any side of the substrate/array to attract the magnetic particles to move laterally towards the magnetic field. Regarding claims 22 and 24, since the present invention describes that the magnetic field generator is a means for exerting a mechanical stress, which also includes a means for exerting a fluid frictional force and means for generating an excitation that forces a lateral movement of the particles and Baselt teaches a magnetic field generator, such magnetic field generator is capable of exerting a fluid frictional force and generating an excitation that forces the particles to move laterally. Regarding claim 31, since Baselt uses the same magnetic field generator for applying a magnetic field as claimed in the present invention, such magnetic field in Baselt would have the same magnetic vector with varying direction as a function of time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson or Baselt in view of Summerton (US 6,060,246) .

Wilson and Baselt have been discussed above.

However, they fail to teach that the second magnetic particle is not bound to any microbiological entities.

Summerton teaches "Capture of .alpha.-Globin RNA. As an illustration of the method, capture particles were prepared by binding morpholino oligomers to the surface of magnetic beads (M-280), as described in Example 3. A first particle contained a U.sub.25 probe (a 25-mer poly-uracil morpholino oligomer, SEQ ID NO: 1) bound via a PEG spacer group and a disulfide linker group. A second particle contained a probe, designated Neu-Probe.TM. 124, complementary to an .alpha.-globin RNA transcript (SEQ ID NO: 2). A third particle, constituting the rapid pairing reagent, contained both probes. ***Also included was M-280 beads having no attached probes, as a control for nonspecific sticking to the particles".*** (see col. 12, lines 45-57).

It would have been obvious to one of ordinary skills in the art to use a magnetic bead having no attached probes as taught by Summerton for use as a control for nonspecific sticking to the particles as a control particle in the method of Wilson or

Baselt since these references all teaches using multiple different magnetic particles for separating different analytes in a sample.

Claims 27, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson or Baselt in view of Mirkin (US 6,984,491).

Wilson and Baselt have been discussed above.

However, they fail to teach a capture reagent for capturing both first target-first particle complex and second target-second particle complex; and that the second microbiological entities include capture molecules while the first microbiological entities are target molecules.

Mirkin teaches a first particle coupled to a capture molecule and a second particle coupled to a target molecule. The capture molecule and the target molecule hybridize. (see figure 1). Mirkin also teaches that the first particle and the second particles can be magnetic. (see col. 37, lines 44-47). Mirkin also teaches that the first particle coupled to a first nucleic acid sequence hybridizes to a part of a capture molecule and a second particle coupled to a second nucleic acid sequence hybridizes to a second part of the capture molecule. (see fig. 3).

Since it is well known in the art as taught by Mirkin that different assay configurations can be applied using two magnetic particles, it would have been obvious to one of ordinary skills in the art to incorporate the concept of different assay configurations as taught by Mirkin in the method of Wilson or Baselt so that nucleic acids can be manipulated using different magnetic particles.

Response to Arguments

Applicant's arguments filed March 30, 2010 have been fully considered but they are not persuasive.

Regarding the 102 rejections by Wilson and Baselt, Applicants argue that Wilson and Baselt fail to teach any means for acting on first and second particles to cause the first and second particles to exert a mechanical stress on bindings between the first and second microbiological entities to distinguish between the bindings of different strengths. Applicants further submit that Baselt does not disclose first and second particles.

The present claims recite that the means [for acting on first and second particles to cause the first and second particles to exert a mechanical stress on bindings between the first and second microbiological entities to distinguish between the bindings of different strengths] is a magnetic field generator. Wilson and Baselt both disclose using magnetic field generators. Thus, the magnetic field generators in Wilson and Baselt should be able to perform the same functions as claimed in the present invention.

Applicants further argue that in Wilson and Baselt, the magnetic field generator does not act on the first and second particles to cause the first and second particles to exert a mechanical stress on bindings between the first and second microbiological entities to distinguish between the bindings of different strengths. In Wilson, the first particles are attached to first acceptor and the second particles are attached to second acceptors. The first acceptor and second acceptor are not bound together and so there

is no binding between them and they cannot correspond to the first and second microbiological entities of claim 18.

Claim 18 does not require that the first and second microbiological entities to be bound to the first and second magnetic particles. Claim 18 is a product claim which requires first particles, second particles and at least one of which is magnetic and a means for acting on the first and second particles to cause the first and second particles to exert a mechanical stress on bindings between the first and second microbiological entities to distinguish between the bindings of different strengths, the means…comprising at least a magnetic field generator. Furthermore, the claims in the present invention as now recited are not drawn to a method and they do not require the functional steps of the method of causing the first and second particles to exert a mechanical stress on bindings between the first and second microbiological entities . Furthermore, the present specification exemplifies that the magnetic field generator is one of the means for performing the function of causing a mechanical stress and Wilson and Baselt teach such magnetic field generator which could be used to perform the same functions in the method of the present invention.

Applicants request an explanation of how Wilson and Baselt teach each and every feature of claims 20 and 29 which recites that "the first particles are coupled to the first microbiological entities and the second particles are coupled to the second microbiological entities".

The present claims are drawn to a tool or a product which comprises first particles, second particles, at least one of which is magnetic and a means for acting on

the first particle and second particle… and claims 20 and 29 require that "the first particles are coupled to the first microbiological entities and the second particles are coupled to the second microbiological entities". Please note that the claims do not require that the first and second microbiological entities are bound to each other because these claims are not method claims. Although the means recites a functional step which states that "bindings between the first and second microbiological entities", such method step does not happen in these claims. Therefore, Wilson's and Baselt's teachings of a first particle having a first microbiological entity attached thereto and a second particle having a second microbiological entity attached thereto and one of those particles is magnetic satisfy the requirement of claims 20 and 29.

Regarding claim 31, Applicants requests an explanation of how or why it is known that Wilson and Baselt use the same magnetic field generator for applying magnetic field as claimed in claim 31.

Claim 18 recites that "the means for … comprises at least a magnetic field generator" which does not recite any structural limitation which is different from the one used in Wilson or Baselt and therefore it can be concluded that Wilson and Baselt use the same magnetic field generator as that of the present invention. For claim 31, since Wilson and Baselt use the same magnetic field generator, such magnetic field in Baselt and Wilson would have the same magnetic vector with varying direction as function of time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641

/Jacob Cheu/
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